Main, B., McNair, A., Haworth, S., Rooshenas, L., Hughes, C. W., Tierney, P., Donovan, J., Thomas, S., & Blazeby, J. (2018). Core information set for informed consent to surgery for oral or oropharyngeal cancer: A mixed-methods study. *Clinical Otolaryngology*, *43*(2), 624-631. https://doi.org/10.1111/coa.13037

Core information set for informed consent to surgery for oral or oropharyngeal cancer: a mixed methods study

B G Main[1,2], A G K McNair[1], S Haworth[1,3], L Rooshenas[1], C W Hughes[2,3], P Tierney[2], J L Donovan[1], S J Thomas[2,3], J M Blazeby[1,2]

[1]School of Social and Community Medicine, University of Bristol; [2]University Hospitals Bristol NHS Foundation Trust; [3]School of Oral and Dental Sciences, University of Bristol

Corresponding author

Barry G Main

Centre for Surgical Research

School of Social and Community Medicine

University of Bristol

Canynge Hall

39 Whatley Road

Bristol

BS8 2PS

Tel: 0044 (0)117 331 3932

Email: b.g.main@bristol.ac.uk

Abstract

Objectives

To develop a core information set for informed consent to surgery for oral/oropharyngeal surgery. A core information set is baseline information rated important by patients and surgeons, and is intended to improve patients' understanding of the intended procedure.

Design

A mixed methods study. Systematic reviews of scientific and written healthcare literature, qualitative interviews and observations, Delphi surveys, and group consensus meetings identified information domains of importance for consent.

Setting

A regional head and neck clinic in the United Kingdom. Questionnaire participants were recruited from around the UK.

Participants

Patients about to undergo, or who had previously undergone, surgery for oral/oropharyngeal cancer. Healthcare professionals involved in the management of head and neck cancer.

Main outcome measures

The main outcome was a core information set

Results

Systematic reviews, interviews and consultation observations yielded 887 pieces of information that were categorised into 87 information domains. Survey response rates were 67% (n=50) and 71% (n=52) for patient and healthcare professional groups in round one. More than 90% responded in each group in the second round. Healthcare professionals were more likely to rate information about short-term or peri-operative events as important while patients rated longer-term issues about survival and quality of life. The consensus-building process resulted in an agreed core information set of 13 domains plus two procedure-specific domains about tracheostomy and free flap surgery.

Conclusion

This study produced a core information set for surgeons and patients to discuss before surgery for oral/oropharyngeal cancer. Future work will optimise ways to integrate core information into routine consultations.

Introduction

Cancers of the oral and oropharyngeal cavities are important health problems for which surgery is a potentially curative treatment option. While survival rates are relatively favourable compared to other upper aerodigestive tract cancers, oral/oropharyngeal cancers and their treatment can have potentially long-lasting adverse effects on function and quality of life.[1, 2]

People with cancer want information about their disease and its treatment.[3-6] In general, patients express a desire for as much information as possible but evidence suggests these needs are often left unmet.[7, 8] Patients report being insufficiently informed about sensitive issues including survival and quality of life.[8] This means they are potentially unprepared for the outcomes associated with different treatment options, and their consent to treatment may, therefore, be invalid. Recent UK legislation and updated professional guidance have emphasised the fundamental importance of carefully communicating the information patients need in order to authorise invasive treatments, including surgery.[9] The landmark ruling in *Montgomery* identified inconsistent information provision as a key issue in the practice of obtaining patients' consent.[9] While highlighting these deficiencies in practice, the legal and professional bodies stop short of suggesting specific, effective ways in which patients and surgeons can work together to ensure the informed consent process better meets the needs of all parties.

One potential solution is a core information set for informed consent. Core information sets are defined as consensus-derived minimum sets of information to be discussed with all patients about to undergo given procedures.[10, 11] They are intended to address inconsistent information provision while providing a baseline catalyst for further discussion of importance to the individual patient. This study aimed to produce a core information set for use in consent consultations with patients about to undergo surgery for oral or oropharyngeal cancer.

Methods

Ethical considerations

All participants were provided with detailed written information about the study and gave their written consent. The study was approved by a Research Ethics committee (ref 13/WM/0319).

Core information set development involved three phases of work (Figure 1).

Phase 1. Collating information and exploring stakeholder views

Information and outcomes potentially relevant for discussion before surgery were listed verbatim. Sources reviewed included: Randomised controlled trials and prospective longitudinal studies reporting clinical and patient-reported outcomes of treatments for oral/oropharyngeal cancer, written patient information leaflets provided for patients by hospitals and other organisations, validated quality of life instruments, systematic reviews, published trial protocols, and national policy and guideline documents. Thematic analysis of transcripts of semi-structured interviews and recorded consultations provided additional information. Duplicates were removed as were outcomes unlikely to be important for informed consent to surgery (for example, biological or physiological surrogate end points).

The resulting long list was refined by grouping similar information and outcomes into broader categories called domains. For example, 'overall survival' and 'survival' were combined in a single 'survival' domain. The categorisation of items into domains was carried out independently by three researchers (BM, ST, JMB). Each domain was assigned to one of four global domains describing different stages of the surgical pathway.

Phase 2. Surveying key stakeholders about information priorities

Delphi methods were applied to survey patients, surgeons, and allied health professionals. Each information item was presented in lay language, with medical terminology in parenthesis, alongside a nine-point Likert scale on which participants rated the item's importance for discussion with all patients about to undergo surgery for oral/oropharyngeal cancer. Participants rated items from 1-to-9 where 1 was 'not essential', and 9 considered 'absolutely essential'. The questionnaire was piloted by a nurse and two lay people for clarity of presentation, instruction, and validity.

Surgeons were identified from the websites of the British Association of Oral and Maxillofacial Surgeons, and ENT-UK. Clinical nurse specialists and allied healthcare professionals (speech and language therapists and dietitians) were invited to participate *via* the British Association of Head and Neck Oncology Nurses. Patient participants were recruited from a head and neck cancer clinic in Bristol, UK, and included those who had undergone surgery for oral and/or oropharyngeal cancer. Second round questionnaires contained those items retained from the first round, and participants were asked to re-rate each. Alongside each item, participants were given feedback that included their own rating, and the median patients' and healthcare professionals' ratings from round one. Retained items were taken forward to Phase 3.

Phase 3. Defining the core information set

Items retained following analysis of the second round questionnaires were further considered at two consensus meetings in May and October 2015. Participants were asked to rate the importance of each item for pre-operative informed consent. Once all participants had voted, a histogram and descriptive statistics were presented for immediate feedback. Items clearly scoring a majority (≥ 75%) 'yes' or 'no' were retained or discarded respectively. Where there was a bimodal distribution of responses, or the majority voted 'unsure', the item was carried forward to a second round of voting. Voting and discussion continued in this way until a consensus 'in' or 'out' was obtained for each item.

Sample size

There is no agreed method for determining sample size in Delphi studies.[12-14] A pragmatic, approach was taken with the aim of ensuring the participants were representative of the parent populations of interest.

Data analysis

In the questionnaire study, items were retained if they were rated as 'essential' (7-9 on Likert scale) by ≥ 70% of respondents *and* 'not essential' (1-3 on Likert scale) by ≤ 15%. The rationale was for there to be a sufficient proportion of participants agreeing an item's importance *and* a small number disagreeing its importance to allow inclusion. Other score distributions were taken to indicate a lack of consensus allowing the item to be carried forward. The responses from the different groups were first considered separately for comparative purposes. However,

decisions about which items were carried forward were based on the responses of the entire study population. That is, items considered important by patients *or* (as opposed to *and)* healthcare professionals were kept in so that information of particular importance to a given group was not lost.

Results

Phase 1. Collating information and exploring stakeholder views

The review of data sources, and interviews with patients and surgeons, generated a long list of 887 pieces of information and clinical and patient-reported outcomes. This was reduced to 565 by removing duplicates. Retained items were grouped into 87 domains that were further organised into four global domains: 'before the operation', 'the operation and being in hospital', 'recovery and longer-term quality of life', and 'effectiveness of surgery'.

Phase 2. Surveying key stakeholders about information priorities

Fifty patients, 17 clinical nurse specialists or allied health professionals, and 38 surgeons completed round one questionnaires. This represented 67%, 85%, and 58% response rates respectively. Fifty-two per cent of patients were male, their average age was 63.9 years, and 48% were retired. All had undergone surgery for oral or oropharyngeal cancer an average of 30.1 months previously. Approximately one third of the cohort had received radiotherapy and/or chemotherapy in addition to surgery. All but one of the surgeons were male. The majority were oral and maxillofacial surgeons and had been qualified as consultants for more than 10 years. The baseline characteristics of the participants are summarised in Tables 1 and 2.

In round one, patient participants retained 62 out of 87 domains. Items rated 'essential' by the highest proportions of respondents included those about the likelihood of clear resection margins, distant metastases or recurrence of disease, intra-operative damage to nerves in the neck and face, and immediate post-operative swallowing function. Items discarded by the patient group included intra- and peri-operative events including risk of in-hospital mortality, adverse cardiac events, and how the tumour would be resected. Items about shortness of breath, weight, nausea, vomiting, and diarrhoea were discarded.

Forty-five items were retained by the healthcare professionals in round one. The items rated 'essential' by the highest proportion included those about incisions, tracheostomy, flap reconstruction and its potential problems, immediate post-operative impact on swallowing, speech and chewing, and longer-term speech problems. Items falling below the threshold for inclusion in the second round included those about pre-operative assessment, anaesthesia, and intra-operative, peri-operative, and 30-day mortality. Items about constitutional symptoms and psychosocial issues including normal daily activities, self-esteem, and relationships were discarded. The ten items ranked highest by the participants are presented for comparison in Table 3.

Forty-nine patients, 16 clinical nurse specialists, and 35 surgeons completed the second round questionnaires. This represented attrition rates of 2%, 6%, and 8% respectively. Forty-three out of 45 items were retained by the patient participants in round two. The items rated as 'essential' by the largest proportion of respondents were 'the likelihood that the whole tumour will be removed (margins)', and 'ability to control saliva without drooling'. Other items rated as 'essential' by the majority of respondents included chewing, swallowing, and speech, those about flap reconstruction and its potential problems, and items about operative and peri-operative issues including inoperability and surgical adjuncts (drains and drips). The four items discarded by patient participants in this round were 'long term effects on shoulder function', 'longer term pain', 'change in appearance of face or neck', and 'physical ability'.

The healthcare professionals' responses to the second round questionnaire resulted in 40 items being retained for further consideration, and five being discarded. All respondents rated items about tracheostomy, post-operative chewing and swallowing, post-operative speech, longer-term speech, long-term shoulder function, and flap reconstruction as 'essential'. Items rated 'essential' by more than 95% of respondents included those about incisions, drips, potential problems with flap reconstruction, and cranial nerve damage. Items discarded included those on peri-operative complications (e.g. thromboembolism), re-admission to hospital because of complications, chyle leak, and aspects of long-term quality of life. Table 4 summarises the ten highest rated items in the second round questionnaires. Further analysis of retained items,

including merging of similar issues, resulted in 22 domains for discussion in the consensus meetings.

Phase 3. Defining the core information set

The two consensus meetings were attended by 14 patients with 11 carers, and eight healthcare professionals respectively. Following the first round of anonymised voting by patients, eight (of 22) domains were retained for inclusion in the core information set. Seven domains were discarded, and the remaining seven taken forward for further discussion and voting. The healthcare professionals retained 11 domains, none were discarded by a majority, and the remaining 11 were further considered by discussion and voting. The results of the first round voting at each meeting are summarised in Table 5. Between voting rounds, discussion at both meetings resulted in the merging of some domains (e.g. 'mouth opening' was felt by the patient group to be covered by the 'speech' and 'chewing and swallowing' domains). A final core information set consisting of 13 domains was produced. Two procedure-specific domains were included for discussion with patients who were likely to undergo these interventions (tracheostomy and free-flap reconstruction) (Table 6).

Discussion

Synopsis of key findings

This mixed-methods study developed a core information set for discussion with patients about to undergo surgery for oral/oropharyngeal cancer. It includes information domains rated important by patients and healthcare professionals, and is intended to serve as a first step in improving the way surgeons discuss operations with patients. The work identified key areas of patient information need, including survival and disease recurrence, which may hitherto have been unmet in consultations before surgery. We suggest that the core information set be used as the basis for improving communication that helps patients decide whether or not to provide their informed consent to surgery.

Strengths and weaknesses of the study

A wide range of sources of potentially relevant information were included in the development of the core information set. The work involved in-depth analyses of scientific literature, written patient information leaflets, interviews with patients and surgeons, and recordings of consultations. The final core information set was defined through an iterative consensus-building process that involved over 100 patients and healthcare professionals. The application of a mixed-methods approach resulted in the identification of key areas of potentially unmet information need among the patient participants that may have been missed otherwise. There are, however, potential limitations associated with the approach taken. Consultation observations took place at one centre. Sampling from more than one centre may have revealed a diversity of practice important to the overall findings. The risk of bias must be considered. Response rates to the questionnaire study were relatively favourable compared to similar studies but it is feasible that non-responders would value different information as being more important.[10] Their experiences of adverse events, for example, may have been higher. It is also acknowledged that our approach is labour and time intensive. Further work will include identifying areas of commonality between different core information sets (e.g. different areas of surgical oncology) and methods for streamlining the phases of core set development (e.g. rapid review methods).

Comparisons with other studies

Studies have demonstrated the often unmet information needs of people with head and neck cancer.[15] Rogers, for example, used a patient concerns inventory to identify key areas of need among patients attending follow-up clinics. In particular, key quality-of-life issues including concerns about dental health, were commonly selected by patients for discussion.[16] Few studies have triangulated data about information needs obtained from multiple sources using a mixed-methods approach such as reported in this paper. Investigating the issue in this way recognises the complexities of informed consent consultations. The core information set thus defined will inform work that aims to improve these consultations by addressing problems in previous attempts at doing so. A systematic review of interventions to improve informed consent showed that most studies were poorly developed, with little theoretical basis for what information about the intended procedure was included in the informed consent interventions.[17] The review highlighted the need to involve all key stakeholders in the development, implementation and evaluation of interventions. The core information set model aims to address this by involving patients and healthcare professionals at each of these stages. The concept has, in addition to this study, been applied in oeosphageal cancer, and work in other areas of surgical oncology are being analysed.[10]

Clinical applicability of the study

A recent landmark legal ruling reignited the discourse on informed consent in the UK.[9] Professional bodies responded to the *Montgomery* case with updated guidelines outlining expected standards of care by surgeons seeking the informed consent of patients.[18-20] The disclosure and subsequent discussion of information that are intended to guide patients through the consent process were highlighted as important deficiencies in clinical practice. In particular, inconsistencies in information provision about a given procedure and failure to address the subjective, or material, needs of individuals were identified as key areas for improvement. A large, prospective study of patients' satisfaction with information provision in head and neck surgical oncology identified that many were not prepared for the degree of functional impairment following surgery.[21] In addition, inconsistencies in information-disclosure practices at different centres was highlighted as an issue.

Core information sets are a starting point at addressing this issue. They are not intended as a panacea, nor is a check-list approach to informed consent consultations being advocated. Instead, they will form the basis of future work that explores how best to incorporate core information sets into encounter tools that guide patients, their carers, and clinicians through the information that is needed to make an informed choice about whether or not to authorise a treatment recommendation.[22] Core information sets may additionally help improve the quality of written healthcare information provided for patients by hospitals and other organisations. These resources have been shown to be of poor quality, and lacking information of importance to patients.[23, 24] The aim is that by including information of importance to key stakeholders, unmet information needs and variations in practice that have been identified as important, will be addressed.

References

1Mehanna HM, Morton RP. Deterioration in quality-of-life of late (10-year) survivors of head and neck cancer. Clin Otolaryngol. 2006;31(3):204-11.
2UK CR. Cancer survival for common cancers 2017. Available from: https://www.cancerresearchuk.org/health-professional/cancer-statistics/survival/common-cancers-compared.
3Blanchard CG, Labrecque MS, Ruckdeschel JC, Blanchard EB. Information and decision-making preferences of hospitalized adult cancer patients. Soc Sci Med. 1988;27(11):1139-45.
4Butow PN, Dunn SM, Tattersall MH, Jones QJ. Patient participation in the cancer consultation: evaluation of a question prompt sheet. Ann Oncol. 1994;5(3):199-204.
5Caminiti C, Diodati F, Filiberti S, Marcomini B, Annunziata MA, Ollari M, et al. Cross-cultural adaptation and patients' judgments of a question prompt list for Italian-speaking cancer patients. BMC Health Serv Res. 2010;10:16.
6Sutherland HJ, Llewellyn-Thomas HA, Lockwood GA, Tritchler DL, Till JE. Cancer patients: their desire for information and participation in treatment decisions. J R Soc Med. 1989;82(5):260-3.
7Sainio C, Eriksson E. Keeping cancer patients informed: a challenge for nursing. Eur J Oncol Nurs. 2003;7(1):39-49.
8Voogt E, van Leeuwen AF, Visser AP, van der Heide A, van der Maas PJ. Information needs of patients with incurable cancer. Support Care Cancer. 2005;13(11):943-8.
9Sokol DK. Update on the UK law on consent. BMJ. 2015;350:h1481.
10Blazeby JM, Macefield R, Blencowe NS, Jacobs M, McNair AG, Sprangers M, et al. Core information set for oesophageal cancer surgery. Br J Surg. 2015;102(8):936-43.
11Main BG, McNair AGK, Huxtable R, Donovan JL, Thomas SJ, Kinnersley P, et al. Core information sets for informed consent to surgical interventions: baseline information of importance to patients and clinicians. BMC Med Ethics. 2017;18(1):29.
12Black N, Murphy M, Lamping D, McKee M, Sanderson C, Askham J, et al. Consensus development methods: a review of best practice in creating clinical guidelines. J Health Serv Res Policy. 1999;4(4):236-48.
13Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. J Adv Nurs. 2000;32(4):1008-15.
14Keeney S, Hasson F, McKenna H. Consulting the oracle: ten lessons from using the Delphi technique in nursing research. J Adv Nurs. 2006;53(2):205-12.
15Jabbour J, Milross C, Sundaresan P, Ebrahimi A, Shepherd HL, Dhillon HM, et al. Education and support needs in patients with head and neck cancer: A multi-institutional survey. Cancer. 2017.
16Rogers SN, El-Sheikha J, Lowe D. The development of a Patients Concerns Inventory (PCI) to help reveal patients concerns in the head and neck clinic. Oral Oncol. 2009;45(7):555-61.
17Kinnersley P, Phillips K, Savage K, Kelly MJ, Farrell E, Morgan B, et al. Interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures. Cochrane Database Syst Rev. 2013(7):CD009445.
18England TRCoSo. Good surgical practice 2015 [March 2017]. Available from: https://www.rcseng.ac.uk/surgeons/surgical-standards/professionalism-surgery/gsp.
19Health Do. Reference Guide to Consent for Examination or Treatment 2015 [8th March 2017]. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf
20Council TGM. Consent: patients and doctors making decisions together. London: GMC; 2008.
21Bozec A, Schultz P, Gal J, Chamorey E, Chateau Y, Dassonville O, et al. Evaluation of the information given to patients undergoing head and neck cancer surgery using the EORTC QLQ-INFO25 questionnaire: A prospective multicentric study. Eur J Cancer. 2016;67:73-82.

22Elwyn GM, VM. Tools to engage patiets in clinical encounters. In: Elwyn GE, A Thompson, R, editor. Shared decision making in health care Achieving evidence-based patient choice. 3rd ed. Oxford: Oxford University Press; 2016. p. 57-63.
23Blencowe NS, Strong S, McNair AG, Howes N, Elliot J, Avery KN, et al. Assessing the quality of written information provision for surgical procedures: a case study in oesophagectomy. BMJ Open. 2015;5(10):e008536.
24McCartney M. Patient information leaflets: "a stupid system". BMJ. 2013;347:f4748.

Table 1. Clinical and socio-demographic details of patient participants in the questionnaire study

	Participants (*n*=50)
Mean age (years)*	63.9 (37-88)
Male	26 (52)
Female	24 (48)
Educational level¶	
Basic	20 (40)
Further	30 (60)
Employment status	
Working full time	12 (24)
Retired	24 (48)
Housewife/househusband	5 (10)
Unemployed due to sickness or disability	4 (14)
Unemployed and seeking employment	0
Voluntary work	1 (2)
Other	1(2)
Mean time since primary surgery (months)*	30.1 (3-116)
Experienced complications requiring reoperation	3 (6)
Length of hospital stay (weeks)	
<2	41 (82)
2-3	4 (8)
3-4	4(8)
>4	1 (2)
Neoadjuvant or adjuvant treatment	
Chemotherapy	0
Radiotherapy	5 (10)
Chemoradiotherapy	9 (18)

*Values in parentheses are percentages unless indicated otherwise. *Values are mean (range). ¶Basic education is up to the age of 16 years, or completing the General Certificate of Education or equivalent. Further education refers to all additional qualification*

Table 2. Details of the healthcare professionals participating in the questionnaire study

	Participants (*n*=55)
Age (years)	
<21	0
21-30	0
31-40	12 (21.8)*
41-50	20 (36.4)
51-60	19 (34.5)
>60	4 (7.3)
Male	37 (67.2)
Female	18 (32.8)
Profession	
Consultant surgeon	38 (69.1)
Clinical nurse specialist	12 (21.8)
Speech and language therapist	1 (1.8)
Physiotherapist	1 (1.8)
Dietitian	1 (1.8)
Ward nurse/ward Sister	2 (3.6)
Surgical specialty (surgeons only)	
Oral & Maxillofacial	26 (68.4)
Ear, nose and throat	12 (31.6)
Length of time since qualification (surgeons only, years)	
<5	6 (15.8)
5-10	9 (23.7)
>10	23 (60.5)

** Values in parentheses are percentages*

Table 3. Summary of the top ten highest rated items in round one questionnaires, ranked by participant group

Patients (*n*=50)	Healthcare professionals (*n*=55)
Item (paraphrased description)	**Item (paraphrased description)**
Resection margins	Tracheostomy
Controlling saliva in the long term	'Flap' reconstruction
Likelihood of distant metastases	Post-operative swallowing
Likely disease-free survival	Post-operative speech
Likelihood of regional recurrence	Post-operative chewing
Likelihood of local recurrence	Need for nasogastric tube
Hypoglossal nerve damage	Damage to accessory nerve
Post-operative swallowing	Longer-term speech problems
Damage to the facial nerve	Problems with 'flap' reconstruction
Damage to accessory nerve	Incisions

Table 4. Summary of the top ten highest rated items in round two questionnaires, ranked by participant group

Patients (*n*=49)	Healthcare professionals (*n*=51)
Item (paraphrased description)	**Item (paraphrased description)**
Margins	Tracheostomy
Ability to control saliva	Chewing and swallowing
Chewing and swallowing	Speech immediately post-operatively
Inoperability	Ability to swallow without choking
Speech, including being understood	Speech, including being understood
Problems with flap reconstruction	Flap reconstruction
Drips, drains, tubes	Long-term problems with shoulder function
Speech immediately post-operatively	Problems with flap reconstruction
Ability to swallow without choking	Incisions
Flap reconstruction	Cranial nerve damage

Table 5. Results of first round voting at the two consensus meetings

	Patients' consensus meeting (n=14)				Healthcare professionals' consensus meeting (n=8)			
Domain name (paraphrased)	**Domain in**	**Domain out**	**Unsure**	**1st round decision**	**Domain in**	**Domain out**	**Unsure**	**1st round decision**
Preparing for surgery	12	0	2	Retain	7	1	Retain	7
Incisions	11	3	0	Re-vote	8	0	Retain	8
Margins	12	2	0	Re-vote	8	0	Retain	8
Flap reconstruction	11	1	2	Re-vote	8	0	Retain	8
Drips, drains, tubes	12	1	1	Retain	6	2	Re-vote	6
Tracheostomy	12	1	1	Retain	8	0	Retain	8
Intensive care	12	0	2	Retain	7	1	Retain	7
In-hospital milestones	5	7	2	Discard	4	4	Re-vote	4
Post-operative pain	9	3	2	Discard	5	3	Re-vote	5
Post-operative swelling	8	4	2	Re-vote	5	3	Re-vote	5
Post-operative bleeding	9	3	2	Discard	5	3	Revote	5
Wound breakdown and infection	10	3	1	Re-vote	7	1	Retain	7
Dying in hospital	5	7	2	Discard	4	4	Re-vote	4
Impact of surgery on speech	12	0	2	Retain	7	1	Retain	7
Impact of surgery on chewing and swallowing	14	0	0	Retain	8	0	Retain	8
Long-term effects of cranial nerve damage	12	1	1	Retain	8	0	Retain	8
Impact of loss of teeth	11	2	1	Re-vote	6	2	Re-vote	6
Impact on ability to open mouth	10	2	2	Re-vote	5	3	Re-vote	5
Impact of surgery on body image	9	2	3	Discard	5	3	Re-vote	5
Impact of surgery on overall quality of life	9	4	1	Discard	4	4	Re-vote	4
Survival	14	0	0	Retain	6	2	Re-vote	6
Chances of the disease coming back	10	3	1	Re-vote	7	1	Retain	7

Table 6. The final core information set

Experience before admission to hospital
• Emotional and physical preparation for surgery
Experience on admission and in hospital
• Where skin incisions will be placed and how the tumour will be removed (surgical access and methods of excision)
• Details of drips, drains, and tubes (surgical adjuncts)
• Description of intensive care, including length of stay
• The likelihood of wound problems (infection and breakdown)[§]
• Details of major or common complications including pain, swelling and bleeding that may require a return to the operating theatre[§§]
Experience after discharge from hospital
• Impact of surgery on chewing and swallowing in the longer term
• Impact of surgery on speech in the longer term
• Long-term effects of any nerve damage (cranial nerves)
• Impact of loss of teeth in the longer term
• Long-term overall quality of life[§]
• An indication of the chances of the disease coming back (recurrence)
• An indication of likely long-term survival
Additional, procedure-specific items
• Information about tracheostomy
• Information about free flap reconstruction

[§] Indicates items rated as important by healthcare professionals but not by patients

[§§] Indicates an item modified by the healthcare professionals to include information of importance in addition to that information rated essential for inclusion by patients

Conflicts of interest

BM – Was funded by a National Institute for Health Research Doctoral Research Fellowship (DRF-2012-05-142)

AM – None declared

SH – None declared

LR – None declared

CH – None declared

PT – None declared

JLD – JLD is a NIHR Senior Investigator

SJT- None declared

JMB - This work was undertaken with the support of the MRC ConDuCT-II (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures) Hub for Trials Methodology Research (MR/K025643/1. JMB is a NIHR Senior Investigator